NOT FOR PUBLICATION CLOSE

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NICHOLAS R. LOVALLO, individually and on behalf of all others similarly situated,

Plaintiff,

v.

PACIRA PHARMACEUTICALS, INC., a Delaware corporation, DAVID STACK, an individual, and JAMES SCIBETTA, an individual,

Defendants.

OPINION
Cv. No. 14-06172 (WHW)

Walls, Senior District Judge

Plaintiff Nicholas R. Lovallo brings this class action against Defendants Pacira Pharmaceuticals, Inc., David Stack, and James Scibetta alleging that they violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 and Rule 10b-5, promulgated under Section 10(b), by making materially incomplete, false, and misleading statements about Pacira's product EXPAREL®. Defendants move to dismiss Plaintiff's amended complaint for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6). The Court decides this motion without oral argument. Fed. R. Civ. P. 78. Defendants' motion is granted.

PROCEDURAL AND FACTUAL BACKGROUND

Except where noted, all facts are taken from Plaintiff's amended complaint. ECF No. 22. Defendant Pacira Pharmaceuticals, Inc. ("Pacira") is a Delaware corporation with its principal executive offices located at 5 Sylvan Way, Suite 100, Parsippany, NJ 07054. *Id.* ¶ 29. Pacira's common stock trades publicly on the NASDAQ Global Select Market under the ticker symbol PCRX. *Id.* ¶¶ 29, 34. Pacira is a pharmaceutical company that manufactures and sells EXPAREL® ("Exparel"), a local anaesthetic that contributed to 89% of the company's revenue

in 2013 and 95% of its revenue in 2014. *Id.* ¶¶ 39, 47. Defendant David M. Stack is the President, Chief Executive Officer, Chairman, and Director of Pacira. He became Pacira's CEO in 2008 and certified the annual and quarterly reports Pacira filed with the U.S. Securities and Exchange Commission ("SEC") during all relevant periods. *Id.* ¶ 30. Defendant James S. Scibetta has served as Pacira's Chief Financial Officer ("CFO") since 2008, began overseeing the manufacture, technology transfer, research, and development of Exparel in 2013, and has served as Senior Vice President of Pacira since 2014. Defendant Scibetta also certified the annual and quarterly reports Pacira filed with the SEC during the relevant periods. *Id.* ¶ 31.

I. The FDA's Approval of Exparel

As a pharmaceutical company engaging in interstate commerce, Pacira's operations are regulated by the United States Food and Drug Administration ("FDA"). *Id.* ¶ 36 (citing 21 U.S.C. § 321(b)). Under the Federal Food, Drug and Cosmetic Act ("FDCA"), drug manufacturers may only distribute drugs into interstate commerce after undergoing an approval process with the FDA. To obtain approval, manufacturers must demonstrate, through clinical trials, the safety and efficacy of a new drug for each intended use or indication. *Id.* ¶ 4 (citing 21 U.S.C. § 355(d)).

On October 28, 2011, the FDA granted a New Drug Application ("NDA") allowing Pacira to distribute Exparel, an injection of bupivacaine, an amide-type local anaesthetic, which is injected into a surgical site at the time of surgery to produce postsurgical analgesia (pain relief). *Id.* ¶¶ 3, 47. The FDA based its approval on clinical studies showing Exparel's effectiveness in two surgical procedures: hemmorhoidectomy (hemorrhoid removal) and bunionectomy (bunion removal). *Id.* ¶ 3. Exparel's FDA-approved labeling does not provide instructions for procedures other than hemmorhoidectomies and bunionectomies and states that

"EXPAREL has not been demonstrated to be safe and effective in other procedures," and that "Exparel is not indicated for pre-incisional or pre-procedural loco-regional anesthetic techniques that require deep and complete sensory block in the area of administration." *Id.* ¶¶ 3, 48, 57. The labeling also states that Exparel has been demonstrated to be an effective pain reliever "only during the first 24 hours following study drug administration." *Id.* ¶ 50. In April 2012, Pacira began selling Exparel. *Id.* ¶ 2.

II. Pacira's alleged misbranding of Exparel

The FDCA prohibits "misbranding" of a drug in interstate commerce. *Id.* ¶ 42 (citing 21 U.S.C. § 331(a)). A drug is misbranded if, among other things, its packaging does not include "adequate directions for use," defined by the FDA as "directions under which the lay [person] can use a drug safely and for the purposes for which it is intended." *Id.* (citing 21 U.S.C. § 352(f); 21 C.F.R. § 201.5). Directions for intended use include, among other things, "oral or written statements by [persons legally responsible for the labeling of drugs]," and misbranding occurs when a drug is, "with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised." *Id.* ¶ 43 (quoting 21 C.F.R. § 201.128).

The amended complaint alleges that, although Exparel received FDA approval based on clinical trials of only two types of surgical procedures, and although Exparel's FDA-approved labeling included instructions only for those two procedures, Pacira and Defendant Stack instructed Pacira's sales employees to market Exparel for use to anesthesiologists and surgeons who performed procedures other than bunion and hemmorhoid removals, and to claim that Exparel provided up to 72 hours of pain relief, rather than 24. *Id.* ¶¶ 58-60. The amended complaint includes statements from confidential witnesses, all former Pacira employees, that

between Exparel's launch in 2012 and February 2014, they were instructed to promote Exparel for these allegedly unapproved uses. *Id.* ¶¶ 60-119. As example, one confidential witness, who worked as a Pacira hospital and surgical account specialist between January 2013 and February 2014, states that he carried two types of promotional materials when advertising Exparel: "leave behind materials," which focused on Exparel's use in hemorrhoidectomy and bunionectomy procedures and which he was allowed to distribute to doctors, and "white papers," which discussed Exparel's use in other procedures and which he could read from but could not leave behind. *Id.* ¶¶ 104-07.

III. The Class Period: February 24, 2014 to April 29, 2015

A. Continued alleged misbranding of Exparel

Plaintiff alleges that Defendants made material misstatements and omissions regarding Exparel during the period between February 24, 2014[1] and April 29, 2015 (the "Class Period"), which caused harm to investors who purchased shares of Pacira common stock during this period. *Id.* at pg. 4, ¶¶ 153-88. On February 25, 2014, Pacira filed its 2013 Form 10-K with the SEC and issued a press release announcing its financial and operating results for fiscal year 2013. *Id.* ¶ 153. The press release announced that Pacira had seen Exparel sales growth "across all procedure types." *Id.* ¶ 154. The 10-K included two statements that Exparel provided pain relief for up to 72 hours. *Id.* ¶¶ 155-56. That same day, Defendants Stack and Scibetta participated in a conference call with investors where Stack told investors that Exparel provided up to 72 hours of pain relief and was used by customers "for an evolving broad spectrum of procedures" beyond bunion and hemorrhoid removal. *Id.* ¶ 158.

[1] The amended complaint later refers to February 25, 2014 as the first day of the Class Period. ECF No. 22 ¶ 37.

On May 1, 2014, Pacira filed its 10-Q for the first quarter of 2014, and Defendant Stack announced in another conference call with investors and analysts that Exparel provided local anesthesia for up to 72 hours and continued to grow in use for surgeries other than hemmorhoid and bunion removal. *Id.* ¶ 168.

B. Pacira's announcement of an Exparel sNDA

On February 27, 2014, Pacira announced positive results from a clinical trial testing Exparel's efficacy as a "femoral nerve block" in total knee arthroplasty, a new surgical procedure. *Id.* 120. On May 7, 2014, Pacira announced that it had submitted a "supplemental new drug application" ("sNDA") with the FDA seeking approval for this new use, targeting an approval date of March 5, 2015. *Id.* ¶ 122. On April 4, 2014, Pacira issued another press release announcing data from the nerve block study and claiming that the data showed a "statistically significant reduction in cumulative pain scores over 72 hours compared to a placebo." *Id.* ¶ 161. Pacira employees, including Defendants Stack and Scibetta, made public statements throughout the class period that Exparel's approval for use as a nerve block would increase Exparel's marketability and revenues for the company. *Id.* ¶¶ 123-25.

C. The FDA Warning Letter

On September 25, 2014, before the NASDAQ opened for trading, Pacira disclosed that it had received a "Warning Letter" from the FDA stating that the FDA had discovered "evidence" that Pacira was promoting Exparel for non-approved uses – uses for which Pacira did not have FDA approval and for which Exparel's label did not provide adequate instructions. *Id.* ¶ 10. The Warning Letter emphasized that Exparel had been approved only for use in bunionectomy and hemmorhoidectomy procedures and stated that Pacira had "misbranded" Exparel in violation of the FDCA by suggesting that it had been demonstrated to be safe and effective for use in other

procedures. *Id.* The Warning Letter also stated that Pacira had issued paid journal advertising containing the "false and misleading" claim that Exparel provided up to 72 hours of post-surgical pain relief, rather than just 24. *Id.* ¶ 12. Following this announcement, Pacira's stock price fell $11.66, or almost 11%, closing at $94.62 per share at the end of the day. *Id.* ¶ 14.

On October 30, 2014, Pacira issued a press release announcing its 2014 third quarter financial results, reporting that revenues had missed their estimates. The company's stock price dropped another $14.70 per share, or nearly 14%, to close at $91.11 per share. *Id.* ¶ 196.

D. Pacira's stock price climbs again

Over the next several months, Defendants announced several positive developments for Exparel that were accompanied by a rise in Pacira's stock price. On November 6, 2014, Pacira announced that an independent study evaluating Exparel's use as a nerve block in total knee anthroplasty in connection with the sNDA had demonstrated lower patient-perceived pain scores and higher pain control satisfaction. *Id.* ¶ 16. On December 2, 2014, Defendant Stack stated during a conference call with healthcare analysts that sNDA nerve block approval would "open[ ] up th[e] entire marketplace" of anesthesiologists to the Exparel sales force. *Id.* ¶ 17.

On February 11, 2015, Pacira issued a press release announcing "resolution of matters pertaining to certain promotional aspects of EXPAREL detailed in a recent Warning Letter" and explaining that Exparel's FDA approval was based only on the bunionecetomy and hemmorhoidectomy effectiveness studies and that Exparel was proven to provide pain relief only for up to 24 hours. *Id.* ¶ 136. On February 24, 2015, Pacira filed its 10-K for fiscal year 2014, further explaining that its resolution of the FDA matter would include a "Dear Healthcare Provider Letter" and corrective journal advertisement clarifying the limited status of Exparel's

FDA approval. *Id.* ¶ 137. Pacira's stock price reached an all-time high the next day, on February 25, 2015, at $121.95 per share.

E. The FDA's rejection of the sNDA

On March 2, 2015, before the NASDAQ opened for trading, Pacira announced receipt of a Complete Response Letter ("CRL") from the FDA rejecting the femoral nerve block sNDA. Pacira's stock price dropped $22.47 per share, or nearly 20% to close out the day at $92.30.

F. The U.S. Attorney's Office subpoena

On April 16, 2015, before NASDAQ opened for trading, Pacira announced that it had received a subpoena from the U.S. Attorney's Office for the District of New Jersey requiring production of documents relating to Pacira's marketing and promotion of Exparel. Pacira's stock dropped another $8.92 per share, or nearly 10%, to end the day at $83.47 per share. *Id.* ¶ 20.

IV. Post-Class Period developments

On April 30, 2015, Pacira suspended its full year 2015 financial guidance, citing the U.S. Attorney's Office investigation, the FDA's claims that Pacira had engaged in improper off-label promotion of Exparel, and the FDA's rejection of the femoral nerve block sNDA. *Id.* ¶¶ 20, 200. Pacira's stock price dropped another $13.64 per share, over 16%, to end the day at $83.47 per share.

On May 28, 2015, after the close of the Class Period, Pacira disclosed that it had held an "End-of-Review" meeting with the FDA about the femoral nerve block sNDA in March 2015. Pacira stated that, "[b]ased upon the FDA guidance that the expected use of EXPAREL will be for a broad spectrum of nerve blocks and not limited to the narrow indication of a single nerve block Pacira plans to conduct additional Phase 3 studies for upper extremity and lower extremity nerve blocks. . . ." *Id.* ¶ 140.

V. The Complaint and Amended Complaint

Plaintiff Nicholas R. Lovallo claims that he purchased Pacira common stock at allegedly "artificially inflated prices" during the Class Period and "was damaged thereby upon the revelation of the partial corrective disclosures and materialization of concealed risks." *Id.* ¶ 28. On October 3, 2014, Plaintiff filed a class action complaint against Pacira, Stack, Scibetta, and Lauren Riker, Pacira's Principal Accounting Officer and Executive Director of Finance, alleging that Defendants had engaged in a scheme to commit securities fraud in violation of Section 10(b) of the Securities Exchange Act of 1934 ("Exchange Act"), 15 U.S.C. § 78j(b), and SEC Rule 10b-5, promulgated under Section 10(b), by making untrue statements of material facts and failing to disclose necessary material facts regarding (a) the FDA-approved uses of Exparel and Defendants' marketing of Exparel for non-approved uses, and (b) Pacira's likelihood of receiving the femoral nerve block sNDA for Exparel. Complaint, ECF No. 1. The complaint also alleged that Stack, Scibetta, and Riker were jointly and severally liable under Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a) for the material misstatements and omissions. *Id.* On May 29, 2015, Plaintiff filed an amended complaint removing Riker as a party and asserting additional factual claims against Defendants, including the confidential witness statements. ECF No. 22.

VI. Defendants' Motion to Dismiss

On July 23, 2015, Defendants filed a motion to dismiss the amended complaint for failure to state a claim under Federal Rules of Civil Procedure 9(b) and 12(b)(6) and the Private Securities Litigation Reform Act ("PSLRA"). Def. Mot. Dismiss, ECF No. 28. Defendants argue that Plaintiff fails to allege they made any material misstatement or omission regarding either (a) Exparel's FDA-approved uses and Defendants' off-label marketing of Exparel or (b) the

likelihood of approval of the femoral nerve block sNDA. Defendants also claim that Plaintiff fails to create a "strong inference of scienter" regarding either topic, as required by 15 U.S.C. § 78u-4(b)(2). Defendants state that Plaintiff's Section 20(a) claims fail for the same reasons and because the complaint fails to plead "particularized facts" that Stack and Scibetta were culpable participants in any fraud.

Plaintiff filed a memorandum in opposition on September 11, 2015, ECF No. 37, and Defendants filed a reply brief in further support of their motion on October 9, 2015. ECF No. 38.

STANDARD OF REVIEW

Under Federal Rule of Civil Procedure 8(a)(2), a pleading must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, 'to state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is plausible on its face "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* "A pleading that offers labels and conclusions or a formulaic recitation of the elements of a cause of action will not do. Nor does a complaint suffice if it tenders naked assertions devoid of further factual enhancement." *Id.* (internal quotations and alterations omitted). "[W]here the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged—but it has not 'shown'—that the pleader is entitled to relief." *Id.* at 679.

In considering the plaintiff's claims, the Court may consider the allegations of the complaint, as well as documents attached to or specifically referenced in the complaint. *See Sentinel Trust Co. v. Universal Bonding Ins. Co.*, 316 F.3d 213, 216 (3d Cir. 2003); Charles A.

Wright, Arthur R. Miller & Mary Kay Kane, Federal Practice and Procedure § 1357 at 299 (3d ed. 2014). "A 'document integral to or explicitly relied on in the complaint' may be considered 'without converting the motion [to dismiss] into one for summary judgment.'" *Mele v. Fed. Reserve Bank of N.Y.*, 359 F.3d 251, 256 n.5 (3d Cir. 2004) (citing *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997)).[2]

A court may also consider and take judicial notice of matters of public record. *Sands v. McCormick*, 502 F.3d 263, 268 (3d Cir. 2007); *Buck v. Hampton Tp. School Dist.*, 452 F.3d 256, 260 (3d Cir. 2006). Such matters of public record may include prior judicial proceedings, *McTernan v. City of York, Penn.*, 577 F.3d 521, 526 (3d Cir. 2009), filings with the SEC, *Schmidt v. Skolas*, 770 F.3d 241, 249 (3d Cir. 2014), and other documents deemed to be public records by law, *Del. Nation v. Pennsylvania*, 446 F.3d 410, 414 n.6 (3d Cir. 2006).

Fed. R. Civ. P. 9(b) requires that "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity. Malice, intent, knowledge, and other condition of mind of a person may be averred generally." "The purpose of Rule 9(b) is to provide notice of the 'precise misconduct' with which defendants are charged" in order to give them an opportunity to respond meaningfully to a complaint, "and to prevent false or unsubstantiated charges." *Rolo v. City Investing Co. Liquidating Trust*, 155 F.3d 644, 658 (3d Cir. 1998), *abrogation on other grounds recognized*, *Forbes v. Eagelson*, 228 F.3d 471 (3d Cir. 2000). To satisfy Rule 9(b), plaintiffs must "plead with particularity the 'circumstances' of the alleged fraud." *Rolo*, 155 F.3d at 658. Rule 9(b) "requires, at a minimum, that plaintiffs support

---

[2] "Plaintiffs cannot prevent a court from looking at the texts of the documents on which its claim is based by failing to attach or explicitly cite them." *Mele v. Fed. Reserve Bank of N.Y.*, 359 F.3d 251, 255 n.5 (3d Cir. 2004).

their allegations of securities fraud with all of the essential factual background that would accompany 'the first paragraph of any newspaper story' – that is, the 'who, what, when, where and how' of the events at issue." *In re Suprema Specialties, Inc. Sec. Litig.*, 438 F.3d 256, 276 (3d Cir. 2006) (quoting *In re Rockefeller Center Prop. Sec. Litig.*, 311 F.3d 198, 217 (3d Cir. 2002)). Plaintiffs "need not, however, plead the 'date, place or time' of the fraud, so long as they use an 'alternative means of injecting precision and some measure of substantiation into their allegations of fraud.'" *Rolo, 155 F.3d at* 658 (citing *Seville Indus. Mach. v. Southmost Mach.*, 742 F.2d 786, 791 (3d Cir.1984)). The Third Circuit has cautioned that courts should "apply the rule with some flexibility and should not require plaintiffs to plead issues that may have been concealed by the defendants." *Id.* (citing *Christidis v. First Pennsylvania Mortg. Trust*, 717 F.2d 96, 99 (3d Cir. 1983)). A plaintiff who alleges securities fraud must "allege facts that give rise to a strong inference of scienter." *Acito v. IMCERA Group, Inc.*, 47 F.3d 47, 53 (2d Cir. 1995); *Burlington*, 114 F.3d at 1418. A plaintiff may establish this strong inference "'either (a) by alleging facts to show that defendants had both motive and opportunity to commit fraud, or (b) by alleging facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness.'" *Burlington*, 114 F.3d at 1418 (quoting *Acito*, 47 F.3d at 52).

The Private Securities Litigation Reform Act ("PSLRA"), 15 U.S.C. § 78u-4(b)(2), specifically addresses the scienter requirement of a § 10(b) claim. It requires that a complaint which asserts a § 10(b) claim must "(1) 'specify each statement alleged to have been misleading [and] the reason or reasons why the statement is misleading' . . . and (2) 'state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.'" *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 321 (2007) (quoting 15 U.S.C. § 78u-4(b)(2)). The plaintiff must plead facts demonstrating that defendants had "a mental state

embracing intent to deceive, manipulate, or defraud." *Rahman v. Kid Brands, Inc.*, 736 F.3d 237, 243 (3d Cir. 2013) (quoting *Tellabs*, 551 U.S. at 319). In determining whether the plaintiff has established an inference of scienter "that is cogent and at least as compelling as any opposing inference of nonfraudulent intent," the Court must "weigh the plausible nonculpable explanations for the defendant's conduct against the inferences favoring the plaintiff" and look at "whether *all* of the facts alleged, taken collectively, give rise to a strong influence of scienter, not whether any individual allegation, scrutinized in isolation, meets that standard." *Inst. Inv. Group v. Avaya, Inc.*, 564 F.3d 242, 267-68 (3d Cir. 2009) (quoting *Tellabs*, 551 U.S. at 323-24) (emphasis in original). This scienter requirement mirrors the "strong inference" requirement of the Second Circuit under Rule 9(b), s*ee Tellabs*, 551 U.S. at 322; H.R. Conf. Rep. No. 104-369, 104th Cong., 1st Sess. 41, 41 (1995), reprinted in 1995 U.S.C.C.A.N. 740, 740; S. Rep. 98, 104th Cong., 1st Sess. 15 (1995), reprinted in 1995 U.S.C.C.A.N. 679, 694, but with one significant difference: under the PSLRA, "'motive and opportunity' may no longer serve as an independent route to scienter." *Avaya*, 564 F.3d at 277. Instead, "a plaintiff properly pleads scienter by alleging facts that 'constitute circumstantial evidence of either reckless or conscious behavior.'" *Gold v. Ford Motor Co.*, 577 F. App'x 120, 123 (quoting *Avaya*, 564 F.3d at 276-77). Recklessness, in turn, is "an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it." *Avaya*, 564 F.3d at 267 n.42. Motive and opportunity, though not sufficient to establish scienter alone, may still support an inference of scienter. "Motives that are generally possessed by most corporate directors and officers do not suffice; instead, plaintiffs must assert a concrete and personal benefit to the individual defendants resulting from this

fraud." *Id.* at 278 (quoting *GSC Partners CDO Fund v. Washington*, 368 F.3d 228, 237 (3d Cir. 2004)) (internal quotations and alterations omitted).

DISCUSSION

Section 10(b) of the Exchange Act and the regulations promulgated under it "prohibit fraud in connection with the sale of securities." *In re Aetna, Inc. Sec. Litig.*, 617 F.3d 272, 277 (3d Cir. 2010). Rule 10b-5 "provides the framework for a private cause of action for violations involving false statements or omissions of material fact." *Weiner v. Quaker Oats Co.*, 129 F.3d 310, 315 (3d Cir. 1997) (citing 17 C.F.R. 240.10b-5). The Third Circuit has held that

> Parties injured by securities fraud may bring a private cause of action under [Section 10(b) and Rule 10b-5], which requires proof of six elements: "(1) a material misrepresentation (or omission); (2) scienter, *i.e.*, a wrongful state of mind; (3) in connection with the purchase or sale of a security; (4) reliance, often referred to in cases involving public securities markets (fraud-on-the-market cases) as 'transaction causation;' (5) economic loss; and (6) 'loss causation,' *i.e.*, a causal connection between the material misrepresentation and the loss."

Aetna, 617 F.3d at 277 (quoting *McCabe v. Ernst & Young, LLP*, 494 F.3d 418, 424 (3d Cir. 2007)). When plaintiffs bring a claim under a "fraud on the market" theory, the court makes rebuttable presumptions "(1) that the market price of a security actually incorporated the alleged misrepresentations, (2) that the plaintiff actually relied on the market price of the security as an indicator of its value, and (3) that the plaintiff acted reasonably in relying on the market price of the security." *Semerenko v. Cendant Corp.*, 223 F.3d 165, 178-79 (3d Cir. 2000) (citing *Zlotnick v. TIE Communications*, 836 F.2d 818, 822 (3d Cir. 1988)).

Section 20(a) of the Exchange Act "imposes joint and several liability on the part of one who controls a violator of Section 10(b)." *Suprema*, 438 F.3d at 284 (citing 15 U.S.C. § 78t). To establish a violation of Section 20(a), "the plaintiff must prove that one person controlled another person or entity and that the controlled person or entity committed a primary violation" of Section 10(b). *Id.* "Where there is no liability for the underlying company under Section 10(b),

there can be no 'controlling person' liability under Section 20(a)." *Avaya*, 564 F.3d at 280 (internal quotation and alterations omitted).

Plaintiff alleges that Defendants violated Section 10(b) and Rule 10b-5 in two ways: first, they marketed Exparel for use in procedures other than bunion and hemmorhoid removals and advertised that the drug provided up to 72 hours of pain relief without disclosing to investors that they were engaging in "off-label" promotion, i.e., without disclosing (a) that the FDA's approval of Exparel was based only on studies of its efficacy in bunionectomies and hemmorhoidectomies and (b) that the drug was demonstrated to provide only up to 24 hours of pain relief. ECF No. 22 ¶¶ 53-54. This created a "material and undisclosed risk of the adverse regulatory action" that eventually arrived in the form of the FDA Warning Letter and U.S. Attorney's Office subpoena. *Id.* ¶ 54. Plaintiff alleges a "fraud on the market" theory, claiming that Pacira's stock traded in an efficient market. *Id.* ¶¶ 224-25. As a result, Defendants' misstatements and omissions caused Pacira's securities to be "overvalued and artificially inflated" until the regulatory actions were disclosed, *id.* ¶ 205, and caused Plaintiff and other class members to purchase Pacira stock during the Class Period at these allegedly inflated prices. Plaintiff and others then suffered damages in the "subsequent decline in the value of the Company's stock when Defendants' prior misstatements and other fraudulent conduct was revealed." *Id.* ¶ 204.

Plaintiff claims that Defendants also violated Section 10(b) and Rule 10b-5 by making optimistic statements about the femoral nerve block sNDA without disclosing that their off-label marketing of Exparel made it unlikely that they would receive FDA approval for this new use. *Id.* ¶ 185. Again, Plaintiff claims that this material omission artificially inflated Pacira's stock price and that the price dropped following the FDA's rejection of the sNDA and Pacira's

subsequent suspension of its 2015 financial guidance, causing harm to investors who bought Pacira stock during the Class Period. *Id.* ¶¶ 204-05.

Defendants do not challenge Plaintiff's allegations of reliance, loss causation, and damages. Defendants also do not deny that they marketed Exparel for what Plaintiff claims are "off-label" uses, that they claimed it provides up to 72 hours of pain relief, that they made optimistic statements about the femoral nerve block sNDA, that their aggressive marketing contributed to Pacira's high stock price, or that the FDA Warning Letter, U.S. Attorney's Office subpoena, and sNDA rejection all led to a drop in the stock price.

Instead, Defendants argue that the amended complaint must be dismissed because Plaintiff fails to plead that they made (a) particularized false statements or omissions of facts (b) that were material (c) with scienter. ECF No. 28 at 13-17. Essentially, Defendants argue that they engaged in all of the alleged misconduct openly: they were transparent about their Exparel marketing strategy and disclosed both the alleged misbranding *and* the actual terms of Exparel's NDA approval to investors well before they received the FDA Warning Letter or U.S. Attorney's Office subpoena. *Id.* Defendants also claim that many of the alleged misstatements identified by Plaintiff – to the extent that they were misstatements – were forward-looking statements or opinions protected by the PSLRA's "safe harbor" provision, 15 U.S.C. § 78u-5. *Id.* at 18-20. Finally, Defendants argue that, despite the statements of confidential witnesses and Plaintiff's allegations that Stack and Scibetta sold large amounts of Pacira stock during the Class Period, the amended complaint fails to state particularized facts giving rise to a "strong inference of scienter." *Id.* at 21.

The Court finds that Plaintiff's allegations are insufficient to withstand this motion to dismiss. Defendants' aggressive marketing of Exparel may expose them to civil and even

criminal sanctions, and Plaintiff adequately pleads that Defendants knew or should have known that their statements about Exparel put them at risk of regulatory action. But Plaintiff does not plead with particularity that Defendants' alleged misrepresentations and omissions about Exparel could materially have misled investors. To the contrary, Defendants demonstrate that they repeatedly disclosed both the FDA's limited approval of Exparel and their aggressive, allegedly "off-label" marketing plan. Plaintiff also fails to allege that Defendants made any misstatements or omissions about the femoral nerve block sNDA. Because Plaintiff does not plead with particularity that Defendants made misstatements or omissions of *material* facts, the amended complaint must be dismissed.

I. The Amended Complaint does not allege that Defendants made particularized material misstatements or omissions regarding the misbranding of Exparel.

A. Plaintiff adequately alleges that Defendants made misstatements and omissions regarding the Exparel misbranding.

As discussed, Defendants do not deny that they engaged in any of the activity challenged by the FDA in the Warning Letter. Instead, they maintain that their marketing of Exparel was lawful. Defendants argue that the FDA's 2011 approval of Exparel, while based only on the bunion and hemmorhoid removal studies, actually applied, without limitation, to general "administration into the surgical site to produce postsurgical analgesia," and that the clinical trial where the FDA found that Exparel only provided up to 24 hours of pain relief also demonstrated an "attendant decrease in opioid consumption" among patients for up to 72 hours. ECF No. 28 at 4, 7.[3]

[3] Defendants maintain that any misbranding of Exparel was unintentional because "Pacira and the FDA interpreted the disclosed Exparel approval and clinical data differently." Pacira has sued the FDA, claiming that the Warning Letter violated the company's First Amendment rights to

Pacira's interpretation of the FDA's approval and the hemmorhoid study may or may not be reasonable; it is not for this Court to decide whether the company's marketing practices actually violated the FDCA. The question is whether Defendants made fraudulent statements or omissions in connection with these practices. Plaintiff alleges that they did.

1. Defendants disclosed their broad marketing practices.

Plaintiff does not specifically allege that Defendants hid their aggressive marketing practices from investors. As the amended complaint itself charges, Defendants told investors on the initial launch of Exparel that Pacira would market the product to "colorectal, general, and plastic surgeons," rather than just to doctors providing bunion and hemmorhoid removals. *Id.* at 15 (quoting ECF No. 22 ¶ 150). Plaintiff also alleges that Defendant Stack publicly stated, during a November 2013 conference, that the FDA's "broad label" approval "provides [Pacira] with the opportunity essentially to talk to every surgeon and have every patient who goes into the operating room as a potential candidate for Exparel therapy," *id.* at 6 (quoting ECF No. 22 ¶ 151), and that Pacira employees reported growth in non-bunionectomy and hemmorhoidectomy procedures throughout 2014. *Id.* ¶¶ 168, 176-78, 82. Defendants also point to public SEC filings where, as early as 2012, they informed investors that Pacira would market Exparel as providing postsurgical pain relief for up to 72 hours and stated that they believed the hemorrhoid clinical trial provided support for this claim. *Id.* (citing ECF No. 28 Ex. 2, 2012 Form 10-K at 8-10; ECF No. 28 Ex. 4, 2013 10-K at 4-5). Defendants also disclosed their intent to "market the product widely (beyond simply bunion and hemmorhoid procedures)" in SEC filings. *Id.* at 8-9, 16 (citing ECF No. 28 Ex. 2 at 5, 14, ECF No. 28 Ex. 4 at 3, 23-24). These public statements and

---

engage in "truthful and non-misleading speech" regarding Exparel's approved uses. *Id.* (citing *Pacira Pharmaceuticals, Inc. v. FDA*, No. 15-cv-07055 (S.D.N.Y.)).

filings – including those cited by Plaintiff in the amended complaint – demonstrate that Defendants made the public aware of their aggressive marketing of Exparel.

2. Defendants disclosed a risk of regulatory action.

Defendants also claim that they "appropriately and repeatedly warned the market of the risks associated with FDA regulation of [Pacira's] product and promotional uses." ECF No. 28 at 3 (citing ECF No. 28 Ex. 4 at 13, 16, 30-33). However, "[w]arnings of possible adverse events are insufficient to make omissions of present knowledge of certain future events legally immaterial." *In re MobileMedia Sec. Litig.*, 28 F. Supp. 2d 901, 930 (D.N.J. 1998) (citing *In re Westinghouse*, 90 F.3d 696, 709 (3d Cir. 1996)).

3. Defendants made misstatements and omissions regarding the FDA's actual terms of approval.

The heart of Plaintiff's claim is not that Defendants simply failed to disclose their marketing practices, nor that they failed to warn investors that misbranding *in general* could expose them to regulatory action, but that Defendants failed to *specifically* disclose that they marketed Exparel for uses and periods of effectiveness beyond those approved by the FDA. ECF No. 22 ¶ 7 ("Defendants recklessly misled investors to believe that Pacira complied with FDA rules and regulations, and falsely attributed Exparel's explosive sales growth to increasing acceptance of the drug for surgical procedures for which it had FDA approval.").

Despite Defendants' claim that that the amended complaint "does not adequately support Plaintiff's allegation that Defendants failed to 'disclose that its clinical trials demonstrated effectiveness only up to 24 hours, and only for two surgical procedures," ECF No. 38 at 3 (citing ECF No. 22 ¶¶ 179, 183, 188), the amended complaint includes numerous specific misstatements or omissions. The complaint lists (a) Pacira's 2013 10-K, filed on February 25, 2014, which

states that "EXPAREL provides continuous and extended postsurgical analgesia for up to 72 hours and reduces the consumption of opioid medications" and that the FDA approved Exparel "for infiltration into the surgical site to produce postsurgical analgesia for up to 72 hours," ECF No. 38 at 15-16, (b) a press release accompanying the 2013 10-K which stated that Pacira "saw a surge [in Exparel sales] across all procedure types . . . fueling rapid growth," (c) a conference call on February 25, 2014 where Defendant Stack allegedly told investors that Exparel provided up to 72 hours of pain relief and was used by customers "for an evolving broad spectrum of procedures" beyond bunion and hemorrhoid removal, *id.* ¶ 158, (d) a May 1, 2014 conference call accompanying the release of Pacira's first-quarter 2014 10-Q where Stack allegedly told investors and analysts that Exparel provided local anesthesia for up to 72 hours and continued to grow in use for surgeries other than hemmorhoid and bunion removal, *id.* ¶ 168, and (e) a May 13, 2014 conference call where Stack allegedly told investors and analysts that Exparel could "turn the pain signal off directly at the site of surgical insult for that 72 hour period of interest" and that Exparel had the "best possible" FDA approval label because Pacira could market Exparel for a wide variety of procedures. *Id.* ¶ 169. According to Plaintiff, these communications included both material misstatements that Exparel provides up to 72 hours of pain relief and material omissions of the fact that Exparel was *only* approved for bunionectomy and hemorrhoidectomy procedures. The Court agrees.

B. Plaintiff does not demonstrate that Defendants' misstatements and omissions were material.

As discussed, however, a misstatement or omission must be "material" to support a Section 10(b) claim. For an omission or misstatement to be "material," it must be "something that would alter the total mix of relevant information for a reasonable investor making an

investment decision." *Burlington*, 114 F.3d at 1425-26. Defendants correctly claim that the identified misstatements and omissions were immaterial and could not have misled investors because Pacira and the FDA both publicly disclosed the actual terms of Exparel's FDA approval.

The Third Circuit has one of the "clearest commitments to the efficient market hypothesis," *In re Merck & Co., Inc. Sec. Litig.*, 432 F.3d 261, 269 (3d Cir. 2005) (quotation omitted), which holds that, in an efficient market, material "information important to reasonable investors (in effect, the market) is immediately incorporated into stock prices." *Burlington*, 114 F.3d at 1425. It follows that, when a plaintiff alleges a "fraud on the market" theory, as Plaintiff does here, ECF No. 22 ¶¶ 224-25, defendants may assert a "truth on the market" defense and argue that "a misrepresentation is immaterial if the information is already known to the market because the misrepresentation cannot then defraud the market." *Ganino v. Citizens Utilities Co.*, 228 F.3d 154, 167 (2d Cir. 2000) (citing *Provenz v. Miller*, 102 F.3d 1478, 1492 (9th Cir. 1996); *Associated Randall Bank v. Griffin, Kubik, Stephens & Thompson, Inc.*, 3 F.3d 208, 213-14 (7th Cir. 1993)); *In re Intelligroup Sec. Litig.*, 527 F. Supp. 2d 262, 293 n.13 (D.N.J. 2007); *Winer Family Trust v. Queen*, 2004 WL 2203709, at *3-4 (E.D. Pa. Sept. 27, 2004). To invoke the defense, Defendants must demonstrate that true information was "transmitted to the public with the degree of intensity and credibility sufficient to effectively counterbalance any misleading impression created by the insiders' one-sided representations." *In re Unisys Corp. Sec. Litig.*, 2000 WL 1367951, at *4 (E.D. Pa. Sept. 21, 2000) (quoting *In re Apple Computer Sec. Litig.*, 886 F.2d 1109, 1116 (9th Cir. 1989)). Although "[t]ruth-on-the-market analysis is intensely fact specific and thus seldom appropriate at the pleading stage." *Payne v. DeLuca*, 433 F. Supp. 2d 547, 559 n.7 (W.D. Pa. 2006) (citing *Ganino*, 228 F.3d at 167), a "truth on the market defense can . . . be granted on a motion to dismiss where the company's SEC filings or other documents

disclose the very information necessary to make their public statements not misleading." *Wallace v. Systems & Computer Technology Corp.*, 1997 WL 602808, at *10 (E.D. Pa. Sept. 23, 1997) (citing *In re Stac Electronics Sec. Litig.*, 89 F.3d 1399, 1410 (9th Cir. 1996)).

The Court agrees with Defendants that any misstatements or omissions about the Exparel's FDA approval status were immaterial because investors were provided with the full terms of the FDA's approval. Pacira's 2012 10-K describes the hemorrhoidectomy and bunionectomy clinical trials and states that "[t]hese two pivotal Phase 3 trials formed the basis of the evidence for efficacy in the NDA for EXPAREL." ECF No. 28 at 7 (quoting ECF No. 28 Ex. 2 at 8). In the same filing, Defendants describe the opioid usage rates in the hemorrhoidectomy trial that led to their 72-hour efficacy claim but also state that "the FDA noted that EXPAREL demonstrated a significant reduction in pain intensity compared to placebo for the first 24 hours" and that "the FDA concluded that between 24 and 72 after the drug administration there was minimal to no difference between EXPAREL and the placebo treatment group on mean pain intensity." *Id.* (quoting ECF No. 28 Ex. 2 at 9). Most significantly, Exparel's FDA-approved Prescribing Information ("PI"), which Plaintiff cites in the amended complaint, states that Exparel demonstrated efficacy only in the hemorrhoidectomy and bunionectomy trials, that "the difference in mean pain intensity between treatment groups" in both trials "occurred only during the first 24 hours following study drug administration," and that Exparel "has not been demonstrated to be safe and effective in other procedures." ECF No. 22 ¶ 49; ECF No. 28 at 14 (citing Exparel Prescribing Information, ECF No. 28 Ex. 6, § 14). The Exparel PI also provides dosing instructions only for hemorrhoidectomy and bunionectomy procedures. ECF No. 22 ¶ 55. Defendants state that the Exparel PI was publicly available on both the FDA website and Exparel's website throughout the Class Period and was referenced in Pacira's 2011 8-K filing

when the FDA approved Pacira's New Drug Application for Exparel. ECF No. 28 at 14 n.5 (citing ECF No. 28 Ex. 1, Oct. 31, 3011 8-K at Exhibits 99.1 and 99.2 ("Please see the full [PI] for more details available at www. EXPAREL.com"); FDA website (http://www.accessdata.fda.gov/drugsatfda_docs/label/2011/022496s0001b1.pdf); Exparel website (http://www.exparel.com/pdf/EXPAREL_Prescribing_Information.pdf)).

Plaintiff argues that the truth on the market defense is inappropriate at this stage and is unavailable when the true disclosures are "buried" among other statements, as they were here. ECF No. 37 at 14 (citing *Virginia Bankshares, Inc. v. Sandberg*, 501 U.S. 1083, 1097 (1991); *In re Flag Telecom Holdings, Ltd. Sec. Litig.*, 618 F. Supp. 2d 311, 325 (S.D.N.Y. 2009)). According to Plaintiff, the Exparel PI did not sufficiently disclose the FDA limitations because it "was clearly directed at physicians, not investors," and the FDA and Exparel websites are "not places that investors usually look" for information. *Id.* at 2, 14. Plaintiff also claims that the 2011 8-K referencing the PI was of minimal relevance because it was filed "years before the Class Period." *Id.* at 14-15.

But Courts have routinely dismissed 10(b) claims where defendants made disclosures before the class period. *See*, e.g., *California Public Employees' Retirement System v. Chubb Corp.*, 394 F.3d 126, 156 (3d Cir. 2004) (affirming dismissal of complaint alleging that company falsely claimed that premium rate initiative was successful because "[d]efendants fully disclosed before and throughout the Class Period that the initiative was expected to and was indeed causing the loss of profitable business"); *In re Progress Energy, Inc.*, 371 F. Supp. 2d 548, 552 (S.D.N.Y. 2005) (dismissing complaint alleging that company failed to disclose limitations on use of synthetic fuel credits in part because company disclosed limitations by reference in pre-class period proxy statement). Courts have also rejected arguments that publicly available

information of the sort disclosed here was "too difficult to find to qualify as adequate disclosure." *In re Discovery Laboratories Sec. Litig.*, 2006 WL 3227767, at *11 (E.D. Pa. Nov. 1, 2006) (rejecting claim that FDA warning letters, although publicly available, were insufficient factual disclosures because they "require[d] an understanding of the factual intricacies and detailed internal structure" of the defendant company, and holding that the "'truth on the market' defense does not require that any investor should be capable of finding the information and understanding its significance based on a single Web search" and that the court could assume that "reasonable investors . . . exercise due investment diligence."); *see also Merck*, 432 F.3d at 270-71 (affirming dismissal of Section 10(b) action and rejecting plaintiff's argument that disclosure in defendant company's S-1 "was so opaque that it should not have counted as a disclosure" because it required "close reading[,] an assumption," and several calculations); *Ash v. LFE Corp.*, 525 F.2d 215 (3d Cir. 1975) (dismissing complaint under Section 14 of the Exchange Act where proxy statement disclosed directors' current pension amounts and newly proposed pension amounts but not the difference between the amounts, and declining "to hold that those responsible for the preparation of proxy solicitations must assume that shareholders cannot perform simple subtraction").

The Court considers Defendants' truth on the market defense with caution but finds that Defendants adequately disclosed the actual terms of the FDA's Exparel approval so as to render their misstatements and omissions about Exparel's approval status immaterial. Plaintiff had access to both Pacira's public SEC filings and the Exparel Prescribing Information throughout the Class Period. Plaintiff could see that Exparel was approved for use in only two surgical procedures and was proven to provide only up to 24 hours of pain relief, and that Pacira's aggressive marketing of Exparel put the company at risk of regulatory action. Despite Plaintiff's

conclusory assertion that the website of the federal agency tasked with regulating Exparel and the website of the drug itself were "not places that investors usually look" for information, Plaintiff here was actually "capable of finding the information . . . based on a single Web search." *Discovery Laboratories*, 2006 WL 3227767, at *11. The information was not "buried." Because Plaintiff alleges, and Defendants do not deny, that there was an efficient market for Pacira's stock, ECF No. 22 ¶ 224, the Court will assume that the market reacted to these truthful disclosures when Pacira and the FDA made them and incorporated the heightened risk of regulatory action into Pacira's stock price.

That the market reacted negatively to Pacira's announcement of the FDA Warning Letter does not demonstrate otherwise. In an efficient market, "the materiality of disclosed information may be measured post hoc by looking to the movement, in the period immediately following disclosure, of the price of the firm's stock," *Merck*, 432 F.3d at 269 (quoting *Oran v. Stafford*, 226 F.3d 275, 282 (3d Cir. 2000)), but courts will assume that information is incorporated into the company's stock price the first time it is disclosed. *See id.* at 270-71 (affirming motion to dismiss despite drop in defendant company's stock price following publication of newspaper article about co-payment recognition because, as discussed, defendant company had issued a public filing disclosing the co-payment recognition two months before). In *Merck*, the Third Circuit rejected the plaintiff's attempt to "have it both ways" and argue that "the market understood all the good things that Merck said about its revenue but was not smart enough to understand the co-payment disclosure." *Id.* Similarly, the Court finds that, if the market incorporated the misstatements and omissions cited by Plaintiff to "inflate" Pacira's stock price, it also incorporated the true statements in Pacira's 2011 8-K and in Exparel's Prescribing Information to correct that price.

The Court also notes that Pacira's announcement of the FDA Warning Letter (and, later, the U.S. Attorney's Office subpoena) *did* reveal new information that may have affected the company's stock price – that the FDA (and U.S. Attorney's Office) had launched an investigation into Pacira's marketing practices, making it difficult for the company to maintain those practices and further increasing the likelihood that the company would face civil or criminal penalties – but Plaintiff does not claim that Defendants made any misrepresentations or omissions regarding the investigations themselves.

In any event, as Defendants argue, the market's reaction to the FDA Warning Letter may actually support their defense, since Pacira's stock rebounded and reached its highest price on February 15, 2015, *after* the announcement of the Warning Letter. *See* ECF No. 22 ¶ 18. Plaintiff attempts to explain Pacira's stock price rebound by claiming that Pacira's post-Warning Letter statements "only partially revealed the risks and conditions that had been concealed from investors" and "failed to disclose the extent to which revenue growth and off-label procedures were driven by aggressive and improper misbranding by having the sales force deliberately market Exparel for unapproved uses and by overstating the drug's efficacy." ECF No. 22 ¶ 196. These are the exact actions for which Pacira was criticized in the Warning Letter, though, and Plaintiff fails to identify any particularized statements in Pacira's 10/30/14 post-Warning Letter press release or conference call containing misstatements or omissions. In fact, as the amended complaint alleges, a 10/30/14 Zachs Equity Research report announced that Pacira's third-quarter 2014 revenue had "missed estimates" in part because the Warning Letter accused Pacira of using promotional materials that "improperly suggested the use of Exparel for off-label uses which are not approved by the FDA" and issuing "promotional advertisements [that] violated FDA

requirements by overstating the efficacy of Exparel," demonstrating that at least one analyst had fully digested the information Plaintiff claims was kept hidden. ECF No. 22 ¶ 192.

II. The amended complaint does not allege that Defendants made material misrepresentations or omissions regarding the femoral nerve block sNDA.

Plaintiff's second claim is that Defendants issued press releases on February 27, April 4, and July 31, 2014 and made statements during conference calls on November 19 and December 2, 2014 with "materially false and misleading, incomplete, and omitted material information" regarding the Exparel femoral nerve block sNDA. *Id.* ¶¶ 16, 160-62, 172-73, 184. Plaintiff claims that these communications (a) "falsely reported that the clinical trial for expanded use of Exparel for nerve blocking in knee replacement surgery had robust results demonstrating efficacy and safety," and (b) "conceal[ed] misconduct leading the FDA to reject the sNDA, expecting that Pacira's ultimate use of Exparel will be for a broad spectrum of nerve blocks. . . ." *Id.* ¶¶ 162, 180, 185. Plaintiff states that, when Pacira announced that the FDA had rejected the femoral nerve block sNDA on March 2, 2015, Pacira's stock – artificially inflated by the alleged misstatements and omissions – dropped $22.47 per share, or nearly 20%, causing harm to investors. *Id.* ¶ 19

It is undisputed that the FDA rejected the sNDA. But the amended complaint does not allege anywhere that the sNDA was rejected because the femoral nerve block clinical trials did not have "robust results demonstrating efficacy and safety." Other than Plaintiff's conclusory allegations that Defendants' reports about the trials were "false," there is no indication that the trials were unsuccessful, nor that the trials affected the FDA's decision. Even if the Court were to assume that the reports were "false," then, Plaintiff fails to establish that these reports were material. Even if the reports were material, they are not actionable statements under Section

10(b). "Interpretations of clinical trial data are considered opinions." *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 170 (3d Cir. 2014) (citations omitted). "Opinions are only actionable under the securities laws if they are not honestly believed and lack a reasonable basis." *Id.* (citation omitted). Plaintiff does not claim that Defendants did not believe their reports about the clinical trials or that the reports lacked a reasonable basis.

Similarly, Plaintiff offers only a single factual allegation to support his claim that Pacira's "misconduct [led] the FDA to reject the sNDA:" a May 28, 2015 statement by Pacira that, "[b]ased upon the FDA guidance that the expected use of EXPAREL will be for a broad spectrum of nerve blocks and not limited to the narrow indication of a single nerve block, Pacira plans to conduct additional Phase 3 studies for upper extremity and lower extremity nerve blocks." *Id.* ¶ 140. Plaintiff claims this statement demonstrates that the FDA rejected the femoral nerve block sNDA because (a) Pacira had engaged in off-label promotion in the past, and (b) Defendants had made statements that the sNDA would "open[ ] up" the door to other new procedures. According to Plaintiff, the FDA was afraid that Pacira would engage in further misbranding if allowed to market Exparel for a new procedure, so it rejected the sNDA. *Id.* ¶ 141. Plaintiff's interpretation is far from compelling: consistent with Defendants' claims that a nerve block sNDA would "open up" the door to use in many new procedures, the May 28 statement simply revealed that Pacira would conduct additional clinical trials to seek approval for a greater number of procedures, not that the FDA had rejected the sNDA for any particular reason. Even accepting Plaintiff's interpretation, though, the Court has already found that Defendants did *not* conceal their aggressive marketing of Exparel from investors, nor did they conceal the actual terms of the Exparel's FDA approval. Because Defendants made adequate

disclosures, the Court finds that Defendants' statements about the femoral nerve block sNDA did not "conceal[ ] misconduct leading the FDA to reject the sNDA."

III. Plaintiff establishes a strong inference of scienter.

Because the Court has already found that the amended complaint does not state with particularity that Defendants made misstatements or omissions of material facts, further analysis of the complaint is unnecessary. But because, as the Court will discuss, Plaintiff is granted leave to amend, the Court will address Defendants' claim that the complaint fails to establish scienter.

As explained, the PSLRA requires a complaint alleging a violation of Section 10(b) to "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *Avaya*, 564 F.3d at 253 (quoting 15 U.S.C. § 78u-4(b)(2)). For a claim against a corporate defendant, such as Pacira, the plaintiff must demonstrate "the requisite state of mind on the part of an individual officer alleged to have made, or participated in the making of, false or misleading statements on behalf of the corporation." *City of Roseville Employees' Ret. Sys. v. Horizon Lines, Inc.*, 686 F. Supp. 2d 404, 421 (D. Del. 2009) (citing *Southland Sec. Corp. v. INSpire Ins. Solutions, Inc.*, 365 F.3d 353, 367 (5th Cir. 2004)). Here, considering Plaintiff's allegations "collectively rather than individually," *Avaya*, 564 F.3d at 280, the Court finds that Plaintiff does establish an inference of scienter on the part of Defendants that is "cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Id.* at 267.

A. Plaintiff's insider trading allegations do not demonstrate Defendants' "motive and opportunity."

Though pleading "motive and opportunity" to commit fraud alone is no longer sufficient to establish scienter under the PSLRA, *id.* at 277, it is still a relevant factor. *Id.* at 278. Insider stock sales may demonstrate motive and opportunity if they are unusual in scope or timing.

Burlington, 114 F.3d at 1424. Plaintiff primarily attempts to establish scienter by charging that Defendants Stack and Scibetta each made more than $5 million from the sale of Pacira stock during the Class Period. ECF No. 22 ¶¶ 216-219; ECF No. 37 at 22.

As an initial matter, Defendants claim this allegation is facially insufficient because "[c]lear Third Circuit authority requires Plaintiff to allege in the [amended complaint] the Individual Defendants' total holdings of Pacira stock during the Class Period." ECF No. 38 at 8 (citing *Oran*, 226 F.3d at 289). This is incorrect. The *Oran* court held generally that plaintiffs must provide sufficient "information as to whether the trades were normal and routine for each executive." *Oran*, 226 F.3d at 289 (citation omitted). Defendants' total stock holdings are just one indication of whether the alleged trades are "normal and routine." Also relevant are the "amounts of [defendants'] base compensation" compared to their trading proceeds, *id.*; *Suprema*, 438 F.3d at 277, whether trading practices "remained consistent year-over-year," *Avaya*, 564 F.3d at 279, whether defendants retained a large percentage of their common stock holdings in the company, *id.*, whether the stock sales were "unusual . . . compared to the timing of past trades," *id.* (quoting *In re Alpharma, Inc. Sec. Litig.*, 372 F.3d 137, 152 (3d Cir. 2004)), and whether defendants made their trades automatically under a Rule 10b5-1 trading plan. *Id.*

The amended complaint alleges that Defendant Stack made "an amount greater than 13.6 times [his] $596,540 base salary for 2014" during the Class Period, and that Defendant Scibetta made more than "14.7 times [his] $369,233 base salary" during the Class Period. ECF No. 22 ¶¶ 217, 219. Courts have found much lower ratios of stock sale proceeds to compensation to be probative of scienter. *See*, e.g., *Suprema*, 438 F.3d at 277-78 (sales earning defendant over four times his annual salary probative of scienter). The complaint also alleges that both Individual Defendants sold significantly more Pacira stock during the Class Period than they did before the

Class Period. ECF No. 22 ¶¶ 216, 218. Plaintiff does not allege, however, that Defendants sold large percentages of their Pacira stock or that the timing of the sales was unusual. As Defendants point out, none of their sales were timed around the allegedly misleading statements and omissions, and all of their sales occurred "well below Pacira's class period high price" of $121.95 per share on February 25, 2014. ECF No. 28 at 23 (citing *Greebel v. FTP Software, Inc.*, 194 F.3d 185, 206 (1st Cir. 1999) ("The timing does not appear very suspicious. None of these three key players sold at the high points of the stock price.")).

Most importantly, Defendants say, the SEC filings the amended complaint cites for trading information show that Stack and Scibetta made all of their trades automatically under Rule 10b5-1 automatic trading plans adopted before the beginning of the Class Period. ECF No. 28 at 21-22 (citing ECF No. 22 ¶¶ 217-20; ECF No. 28 Ex. 14, Stack Form 4s; ECF No. 28 Ex. 15, Scibetta Form 4s). Trades made under automatic trading plans are of minimal value in establishing an inference of scienter. *See Avaya*, 564 F.3d at 279; *In re Synchronoss Sec. Litig.*, 705 F. Supp. 2d 367, 410, 410 n.56 (D.N.J. 2010) (evidence of trading under 10b5-1 trading plans "largely irrelevant" to demonstration of scienter); *In re Audible Inc. Sec. Litig.*, 2007 WL 1062986, at *12 (D.N.J. April 3, 2007) ("evidence that . . . stock sales were made via Rule 10(b)5-1 plans . . . would prevent those shares from being considered in the motive and opportunity analysis"). The Court finds that Plaintiffs' trading allegations do not demonstrate that Defendants had motive and opportunity to commit fraud.

B. Plaintiff does allege with particularity that made false statements and omissions knowingly or recklessly.

Plaintiff also attempts to demonstrate that Defendants Stack and Scibetta "either knew or recklessly disregarded that what they were saying was materially, misleading, incomplete, or

omitted information" "[b]y virtue of their positions as CEO and CFO," and because, as CEO and CFO, they signed Pacira's SEC filings. ECF No. 22 ¶¶ 207, 215. But it is not enough "to merely allege that defendants 'knew' their statements were fraudulent or that defendants 'must have known' their statements were false," *GSC Partners CDO Fund v. Washington*, 368 F.3d 228, 239 (3d Cir. 2004), even "because of [their] position[s] within the company." *In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 539 (3d Cir. 1999) (citing *Rosenbloom v. Adams, Scott & Conway, Inc.*, 552 F.2d 1336, 1338-39 (9th Cir. 1977) ("A director, officer, or even the president of a corporation often has superior knowledge and information, but neither the knowledge nor the information necessarily attaches to those positions.")). Plaintiff also points to confidential witness statements that Defendant Stack actively encouraged Pacira's sales force to engage in off-label marketing, ECF No. 22 ¶¶ 208-12, but this simply demonstrates that Stack knew the allegedly fraudulent statements and omissions were made, not that he knew they were false.

More persuasively, Plaintiff claims that Defendants must have known that the statements were false because they had access to the FDA's New Drug Application approval letter and the FDA-approved Prescribing Information already discussed by the Court. *Id.* ¶¶ 213-14. As Plaintiff and Defendants argue at different points in their briefs, the approval letter and PI clearly state the limits of Exparel's approved uses. Despite Defendants' repeated claims that their broad interpretation of the PI is reasonable, *see* ECF No. 28 at 4, 7, the Court finds that Plaintiff pleads adequate facts to create a strong inference that Defendants knew or recklessly disregarded that their statements about Exparel were not supported by the FDA. This does *not* mean that Defendants intended to defraud investors – as discussed, Plaintiff and other investors also had access to the PI, so Defendants' false statements were immaterial to investors – but Plaintiff

adequately alleges that Defendants knew or should have known that the statements were false or misleading.

IV. Plaintiff does not allege a violation of Section 20(a).

"Where there is no liability for the underlying company under Section 10(b), there can be no 'controlling person' liability under Section 20(a)." *Avaya*, 564 F.3d at 280 (internal quotation and alterations omitted). Because the amended complaint fails to state a claim under Section 10(b), it also fails to state a claim against Defendants Stack and Scibetta under Section 20(a).

V. Plaintiff is entitled to amend the complaint.

If a complaint fails to state a claim upon which relief can be granted, a plaintiff should ordinarily be granted the right to amend his complaint. The Supreme Court has instructed that:

> The grant or denial of an opportunity to amend is within the discretion of the District court, but outright refusal to grant the leave without any justifying reason . . . is not an exercise of discretion; it is merely abuse of that discretion and inconsistent with the spirit of the Federal Rules.

Foman v. Davis, 371 U.S. 178, 182 (1962). In the Third Circuit, plaintiffs whose complaints fail to state a cause of action are entitled to amend their complaint unless doing so would be inequitable or futile. *Fletcher-Harlee Corp. v. Pote Concrete Contrs., Inc.*, 482 F.3d 247, 252 (3d Cir. 2007). In *Shane v. Fauver*, 213 F.3d 113 (3d Cir. 2000), the Third Circuit stated:

> [W]e suggest that district judges expressly state, where appropriate, that the plaintiff has leave to amend within a specified period of time, and that application for dismissal of the action may be made if a timely amendment is not forthcoming within that time. If the plaintiff does not desire to amend, he may file an appropriate notice with the district court asserting his intent to stand on the complaint, at which time an order to dismiss the action would be appropriate.

Shane, 213 F. 3d at 116 (citing *Borelli v. City of Reading*, 532 F.2d 950, 951 n.1 (3d Cir. 1976)).

Allowing Plaintiff to amend the complaint in this case would not be futile or prejudicial. The case essentially involves one question: whether public disclosures of the actual terms of

Exparel's FDA approval, including the Prescribing Information referenced in Pacira's 2011 8-K and available on the FDA and Exparel websites, were sufficient to notify investors that Defendants' marketing practices put the company in danger of regulatory action. Based on the allegations in the amended complaint, documents incorporated by reference in the complaint, and publicly filed corporate disclosures, the Court finds that they were. If Plaintiff can demonstrate otherwise, he may be able to adequately plead a cause of action under Section 10(b) and Rule 10b-5 by showing with particularity that Defendants' misrepresentations and omissions were material. The Court will allow him to attempt to do so.

CONCLUSION

Because Plaintiff fails to allege that Defendants made material misrepresentations or omissions, Defendants' motion to dismiss the amended complaint is granted. The amended complaint is dismissed without prejudice. Plaintiff is granted leave to seek to amend within 90 days of this opinion. An appropriate order follows.

DATE: 18 November 2015

William H. Walls
Senior United States District Court Judge